UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS OR PARTIALLY DISMISS THE UNITED STATES' FIRST AMENDED COMPLAINT

Dated: July 17, 2007

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MISCELLANEOUS

INTRODUCTION

Twelve years after the United States began investigating this case, fifteen months after the case was unsealed, and almost one year since discovery commenced, the Government has now filed (without seeking leave) a "First Amended Complaint" ("ComplaintG2")[1] against Abbott—in part to add a new drug (Acyclovir) to its case. As Abbott demonstrates below, the Government's claims relating to Acyclovir are too little, and far too late, and should be dismissed. Indeed, virtually all of the transactions covered in the Government's False Claims Act ("FCA") claims must suffer this same fate because the law—including the Second Circuit's recent decision in *United States v. Baylor University Medical Center*, 469 F.3d 263 (2d Cir. 2006)—makes clear that these claims are barred by the statute of limitations.[2] Even if *Baylor* were inapplicable, many of the Government's claims relate to drugs not mentioned in the relator's complaint, and relation-back for those drugs should not be permitted.[3]

1. Acyclovir Claims

The Government's belated move to add Acyclovir to this case has nothing to do with the discovery of new evidence. In fact, allegations relating to Acyclovir were first made in ComplaintR3, which relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") filed in 1997, nearly *ten years ago*—including allegations that Abbott "marketed the spread" for Acyclovir. The Government's 13th-hour attempt to add these Acyclovir claims, after having expressly declined to do so before, is nothing more than a tactical effort to "raise the stakes" against a defendant that, through discovery, has repeatedly exposed the fallacy of the Government's allegations and representations to this Court. The Court should dismiss the Government's new claims relating to Acyclovir for any of three reasons:

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[1] There are now eight different complaints in the chain that is Abbott's case. A chronology of these filings and other key dates, and their import for Abbott's limitations arguments, is attached hereto as Ex. B.

[2] On the day Abbott was to file this brief, this Court denied Dey Inc.'s motion to dismiss several of the United States' claims based on *Baylor*. *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc.*, No. 05-11084, slip op. at 11-16 (D. Mass. July 17, 2007). Abbott presents this argument for two reasons. *First*, unlike Dey, Abbott has produced evidence demonstrating that the United States' multiple extensions of the seal were prejudicial, and that relation-back would thus be improper here. *Id.* at 16 & n.6; *see also infra* Part II.A. *Second*, Abbott wishes to preserve the issue for appellate review.

[3] This issue was expressly reserved in this Court's most recent decision. *See Ven-A-Care*, No. 05-11084, slip op. at 14 n.5 (noting that parties did not brief issue).

- Because Ven-A-Care's motion to amend its *qui tam* complaint against Abbott to "adopt" the Government's initial complaint—which did not allege claims relating to Acyclovir—was granted on May 16, 2006 (ComplaintR6), there *are no* claims relating to Acyclovir on which the Government can now intervene.

- Because the case law makes clear that the Government's initial complaint was itself an amended pleading under Rule 15, the Government cannot amend as of right under Rule 15(a), and the Court should not grant leave to add claims that are based upon facts the Government has known all along.

- In any event, because the Government cannot show "good cause" to intervene as to Acyclovir claims, as required under the FCA, 31 U.S.C. § 3730(c)(3).

2. The Government's FCA Claims As To The Rest Of The Drugs

In addition to the newly added Acyclovir claims, this motion seeks dismissal of nearly all of the Government's FCA claims on timeliness grounds. Abbott advances two alternate theories:

- The Second Circuit's decision in *Baylor*, which issued after Abbott filed its initial motion to dismiss on July 7, 2006, dramatically affects the viability of the Government's FCA claims. *Baylor* held that a Government complaint in intervention does not relate back to the filing of a relator's complaint. In ComplaintG1, the Government sought damages from January 1, 1991 "continuing through January 2001." (Ex. J. ¶ 51.) ComplaintG2 extends that period through Apr. 30, 2001. (Dkt. 4281 ¶ 110.) Even with that extended date, however, *Baylor*'s holding, coupled with the FCA's six-year statute of limitations, would leave the Government with, at most, claims relating to the time period of March 2000 to Apr. 2001—*just over one year*. (*See* Ex. A, Column 1.)

- Even if the Court were to depart from *Baylor* and allow ComplaintG1 to relate back to the relator's *qui tam* complaints, relation back should be permitted only to the first complaint where a given NDC or J-Code was first pled. At the very least, claims that are untimely with only this limited relation back should be dismissed. (*See* Ex. A, Column 2.)[4]

- In either event, ComplaintR3 is the first possible complaint for relation back because Abbott was dismissed before that, and only re-added in that complaint. (*See* Ex. A, Column 3.)

PROCEDURAL HISTORY

A. Ven-A-Care's *Qui Tam* Complaints (ComplaintR1 – ComplaintR5)

On June 23, 1995, Relator Ven-A-Care filed a *qui tam* action under seal in the Southern District of Florida against a number of drug manufacturers. That complaint, ComplaintR1, alleged that Abbott

[4] Because this motion raises different timeliness grounds for dismissal of various plaintiffs' FCA claims, Abbott has attached as Ex. A a chart that explains what claims would remain viable on pure timeliness grounds, depending upon which of Abbott's arguments the Court accepts.

provided false price information for 19 specific National Drug Codes (NDCs).[5] Only five of these NDCs appear in the Government's March 2006 complaint-in-intervention, Complaint G1. (*Compare* Ex. C at 21-27 *with* Ex. J at 10-11.) On March 28, 1997, Ven-A-Care filed with the Southern District of Florida a notice "voluntarily dismiss[ing], without prejudice … ABBOTT LABORATORIES" from the *qui tam*, and its ComplaintR2, which did not name Abbott as a defendant. (*See* Ex. D; Ex. E at 2.)[6]

On August 12, 1997, Ven-A-Care filed its ComplaintR3, re-inserting Abbott. This complaint re-alleged claims relating to the 19 NDCs that had been part of relator's earlier, dismissed *qui tam* against Abbott. It also added NDCs *and* HCPCS J-Codes to its causes of action against Abbott. (*See* Ex. F at 25-27, 39-40, 66-71, 118-23.) Fourteen of the NDCs and seven of the J-Codes contained in ComplaintR3 were included in ComplaintG1; ComplaintG2, at issue here, seeks to add two NDCs of Acyclovir that were contained in this ComplaintR3. (*Compare* Ex. F at 27, 39-40, 66-71, 118-23 *with* Ex. J at 10-11.)

On December 9, 1999, Ven-A-Care filed its ComplaintR4. (Ex. G.) ComplaintR4 did not add or subtract any NDCs or J-Codes as to Abbott. About three years later, on December 11, 2002, Ven-A-Care filed its ComplaintR5. (Ex. H.) Although this complaint added little in the way of specific allegations, it did—in the form of an 82-page exhibit—add literally scores of new NDCs to the causes of action against Abbott. Ven-A-Care's exhibit merely listed the names and NDCs of myriad drugs allegedly sold by

[5] The FDA assigns a unique 11-digit, 3-segment number to each drug product, known as the National Drug Code. The National Drug Code identifies the manufacturer or labeler of the drug (first 5 digits), a product code (next 4 digits), and a package size (last 2 digits). Medicaid programs often reimburse drugs based upon National Drug Codes. Plaintiffs here seek damages for both Medicare and state Medicaid programs, based both on these NDCs, and also on 5-digit alphanumeric J-Codes from the Healthcare Common Procedural Coding System ("HCPCS"). HCPCS codes are not necessarily linked to particular drugs or their manufacturers but, instead, identify only a type of drug and its dosage.

[6] Abbott only recently discovered this information. In late June 2007, the Government finally dropped a year-long battle to prevent Abbott from having access to the sealed docket filings from the Southern District of Florida. An examination of those filings revealed Ven-A-Care's dismissal of Abbott. To the best of Abbott's knowledge, neither the United States nor Ven-A-Care ever acknowledged this fact to this Court or to Abbott; to the contrary, the Government misled the Court, asserting that there was nothing in the under-seal file bearing on this case at all—including on issues relating to statutes of limitation and relation-back. (*See* Ex. Z at 4 ("Abbott has failed to explain how the sealed filings bear on whether the FCA permits relation back or whether the United States' Complaint arises 'out of the conduct, transaction, or occurrence set forth or attempted to be set forth' in the relator's original complaint. Abbott has redacted copies of all of the complaints filed in this matter; it has all the information necessary to raise any statute of limitations/relation back arguments it might chose [sic] to make.").)

Abbott. ComplaintG1 sought recovery relating to 25 NDCs first brought into this case on December 11, 2002 by virtue of Ven-A-Care's "kitchen-sink" exhibit. (*Compare* Ex. H at Ex. 6 *with* Ex. J at 10-11.)

B. The Government's Intervention and Ven-A-Care's Adoption of the Government's Initial Complaint (ComplaintG1 and ComplaintR6)

On March 17, 2006, the Government moved for an order severing all claims against Abbott contained in Ven-A-Care's multi-defendant *qui tam* action; the Southern District of Florida granted the Government's motion. That same day, the Government elected to intervene in the severed *qui tam* against Abbott in part, and declined to intervene in part. Specifically, it intervened "in that part of the action which alleges Medicaid and Medicare fraud with respect to Abbott Laboratories, Inc." with respect to 41 specific NDCs and 11 specific J-Codes. (Ex. I at 1-3). This is noteworthy for two reasons:

- The 41 NDCs intervened in did *not* include any codes for Acyclovir, and the Government made explicit that it "decline[d] to intervene in that part of the action against Abbott as to *all other drugs* . . . identified in this action," (*id.* at 3) (emphasis added); and
- Although the Government indicated that it was "intervening" in Ven-A-Care's *qui tam* action, four of the eleven J-Codes it "intervened" in (J2912, J7051, J7110 & J7130) had never been the subject of false claims allegations against Abbott in any of Ven-A-Care's under seal complaints. (*Compare* Ex. I at 2-3 *with* Exs. C, F-H.)

The Government filed its ComplaintG1 against Abbott the same day it filed its notice of intervention, though inexplicably the complaint added four NDCs (00074-7984-36, 00074-7984-37, 00074-7985-09 & 00074-7990-09) not set forth in the NDCs listed in the Government's notice of intervention. (*Compare* Ex. J at 10-11 *with* Ex. I at 1-2.).

Importantly, on the same day that the Government filed its motion to sever, notice of intervention, and ComplaintG1 (March 17, 2006), Ven-A-Care sought "leave to amend its complaint as to Abbott only," resulting in ComplaintR6, "by adopting the United States' Intervention Complaint as Ven-A-Care's complaint against Abbott," thereby dropping any claims relating to NDCs or J-Codes such as Acyclovir that the Government expressly declined to intervene in. (*See* Ex. K). Ven-A-Care's motion for leave was granted on May 16, 2006, with no objection from the Government. (*See* Ex. L.)

C. Transfer of Plaintiffs' Claims to This Court and Ongoing Discovery

On July 11, 2006, the Judicial Panel on Multidistrict Litigation issued a conditional order transferring this case to this Court for pretrial proceedings. On August 3, 2006, the Court issued an Order consolidating this litigation with MDL 1456.

The parties have already engaged in extensive fact discovery in this case. At an October 26, 2006 hearing, this Court established a pre-trial discovery schedule requiring completion of fact discovery by December 31, 2007. Even prior to the October hearing, the parties had engaged in significant discovery. In July and August of 2006, the parties served initial rounds of written discovery, as well as their Rule 26(a)(1) initial disclosures of witnesses, documents, and damages. Abbott began seeking discovery of state Medicaid agencies in December of 2006. The parties began deposition discovery in earnest in January 2007 and have substantially completed the depositions of approximately 30 witnesses—including three individuals (Bruce Vladeck, Nancy-Ann DeParle, and Thomas Scully) who were Administrators of the Centers for Medicare and Medicaid Services ("CMS") during times relevant to the case. In short, while there remains much to be done, there can be no dispute that the parties have expended considerable time and financial resources to complete fact discovery by the established cut-off date.

Importantly, this discovery has in critical respects focused on the NDCs and J-Codes alleged in ComplaintG1 (hereafter, the "Subject Drugs"). For example, Abbott has limited its discovery requests to the United States and state Medicaid agencies for detailed claims data—indisputably relevant to this case—to the Subject Drugs. And when Abbott has not limited its discovery to the Subject Drugs, Plaintiffs have consistently objected to discovery outside of the Subject Drugs as irrelevant and unduly burdensome. (*See, e.g.*, Ex. N at 1-2 (objecting to discovery directed at "drugs other than those listed in the United States' Complaint at issue in the above captioned action"); Ex. O at 2 (standing on general and specific objections relating to Abbott's request for documents relating to CMS' drug reimbursement policy but not specifically mentioning the Subject Drugs).) Abbott's deposition discovery has also focused particular attention on the Subject Drugs. (*See, e.g.*, Ex. P at 143-48, 171-72, 183, 235-36; Ex. Q at 99-100, 138, 157; Ex. R at 76-77, 135-36; Ex. S at 425-26.)

D. The Government's First Amended Complaint (ComplaintG2)

On June 4, 2007, the Government filed its ComplaintG2, at issue here, against Abbott. (Dkt. 4281.) ComplaintG2 retained the FCA allegations regarding the NDCs and J-Codes listed in ComplaintG1, and also added two NDCs for Acyclovir. These NDCs had previously been listed in Ven-A-Care's *qui tam* complaints (starting with the August 12, 1997 ComplaintR3), but the Government expressly declined to intervene in them when it entered the case. (*See* Ex. I at 3.) The Acyclovir transactions the Government seeks to add allegedly occurred between April 22, 1997 and April 30, 2001. (*See* Dkt. 4281 at ¶¶ 104-110.) Notably, when filing ComplaintG2, the Government did not seek leave to amend, but just asserted that it was entitled to amend pursuant to Rule 15(a). (*See* Dkt. 4280.)

ARGUMENT

I. THE CLAIMS RELATING TO ACYCLOVIR SHOULD BE DISMISSED.

In its ComplaintG2, the Government seeks to inject into this case two NDCs for Acyclovir, claiming damages for approximately four years' worth of transactions. The attempt should be rejected for three reasons: (1) there are no Acyclovir claims for the Government to intervene in; (2) the Government did not seek leave to add these claims, and leave should be denied; and (3) in any event, even if these claims could be "intervened" in, and leave to add them were proper, the Government has not shown the requisite "good cause" to do so under the FCA.

A. The Government May Not Intervene In Claims That Ven-A-Care Has Dropped.

The Supreme Court recently confirmed that "[t]he False Claims Act contemplates two types of actions" and "draws a sharp distinction between" the two. *Rockwell Int'l Corp. v. United States*, 127 S. Ct. 1397, 1411 (2007). The Attorney General may bring a civil action against a party alleged to have filed false claims, *see* 31 U.S.C. § 3730(a), or else a private person may bring a *qui tam* action under § 3730(b), that the Government "may elect to intervene and proceed with." *Rockwell*, 127 S. Ct. at 1411. An "action brought by a private person does not become one brought by the Government just because the Government intervenes." *Id.* In this case, the Government is proceeding under § 3730(b), and its ability to pursue claims flows from its right to intervene in claims brought by the relator.

"[O]ne of the most usual procedural rules is that an intervenor is admitted to the proceeding as it stands, and in respect of the pending issues, but is not permitted to enlarge those issues or compel an alteration of the nature of the proceeding." *Vinson v. Wash. Gas Light Co.*, 321 U.S. 489, 498 (1944). In other words, "the intervener still must take the main suit as he finds it . . . in the sense that he cannot change the issues framed between the original parties, and must join subject to the proceedings that have occurred prior to his intervention; he cannot unring the bell." *Hartley Pen Co. v. Lindy Pen Co.*, 16 F.R.D. 141, 153 (S.D. Cal. 1954); *see also Nat'l Ass'n of Reg. Util. Comm'rs v. ICC*, 41 F.3d 721, 729 (D.C. Cir. 1994) ("Intervenors may only argue issues that have been raised by the principal parties; they simply lack standing to expand the scope of the case to matters not addressed" by those parties). In the context of § 3730(b) suits, this basic rule of intervention must limit the Government to the claims presently alleged by the relator against the defendant; *i.e.*, the parties between whom the suit is proceeding. *Cf.* 31 U.S.C. § 3730(b)(5) ("When a person brings a [*qui tam* action], no person other than the Government may intervene or bring a related action *based on the facts underlying the pending action*." (emphasis added)). In other words, if the relator has no claims to be intervened in, then § 3730(b) does not permit the Government to proceed.

Reviewing the procedural history of this case makes clear that the Government may not "intervene" as to the Acyclovir claims, as there *are no* claims relating to Acyclovir that the Government could take over. On March 17, 2006, the Government chose to intervene in this matter with respect to certain specifically identified NDCs and J-Codes that Ven-A-Care had been pursuing (plus four J-Codes that Ven-A-Care had never raised against Abbott). The Government made perfectly clear at the time that it "decline[d] to intervene in that part of the action against Abbott as to *all other drugs* . . . identified in this action." (Ex. I at 3 (emphasis added).) This left Ven-A-Care with the right to pursue the declined claims relating to all of the other declined drug codes, including Acyclovir itself. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004); 31 U.S.C. § 3730(c)(3). Rather than pursue these claims, however, Ven-A-Care chose to move to amend its complaint on March 17, 2006, and to proceed only as to the limited subset of NDCs and J-Codes that were identified in

ComplaintG1; Ven-A-Care's motion to amend its complaint was granted on May 16, 2006. (*See* Exs. K, L.) The Government did not object to Ven-A-Care's decision to abandon those other claims.

Ven-A-Care's decision to amend its complaint by "adopting the United States' Intervention Complaint as Ven-A-Care's complaint against Abbott," resulted in ComplaintR6, which "completely supersede[d]" Ven-A-Care's prior complaints, rendering them a nullity in this case. *Kolling v. Am. Power Conversion Corp.*, 347 F.3d 11, 16 (1st Cir. 2003); *see also Carver v. Condie*, 169 F.3d 469, 472 (7th Cir. 1999) (holding that allegations not included in amended complaint "fell by the wayside"); *Cicchetti v. Lucey*, 514 F.2d 362, 365 n.5 (1st Cir. 1975) ("an amended complaint normally is treated as completely replacing the former pleading"); 6 CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 1476 (2d ed. 1990) ("Once an amended pleading is interposed, the original pleading no longer performs any function in the case . . . ."). Thus, as of June 4, 2007, when the Government purported to amend its own ComplaintG1 to "intervene" in Ven-A-Care's Acyclovir claims, there were no such claims pending—rendering the Government's Acyclovir claims a nullity. The Government, in its capacity as intervenor, was required to take the case as it was, and cannot "unring the bell" by pursuing claims Ven-A-Care abandoned months ago. The Acyclovir claims should be dismissed.[7]

The Government's citation of 31 U.S.C. § 3730(b)(1) in its notice of intervention does not change the result, for any of three reasons:

- The plain language of § 3730(b)(1)—which provides that when a relator brings a *qui tam* action, "[t]he action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting"—does not apply here, as Ven-A-Care's amendment of its complaint to drop claims is not the "dismissal" of an "action" under § 3730(b)(1).[8]

[7] For the same reasons, this Court should dismiss all claims related to the four HCPCS J-codes that *never* appeared in any of the Ven-A-Care *qui tam* complaints, but, rather, were alleged against Abbott for the first time in ComplaintG1. The Government cannot pursue these claims under § 3730(b), either. If the Government wants to bring its own action based on these claims, it must do so under § 3730(a).

[8] Numerous cases interpreting Federal Rule of Civil Procedure 41 (governing when "an action may be dismissed by the plaintiff without order of court") make this point. *See, e.g., Ryan v. Occidental Petrol. Corp.*, 577 F.2d 298, 302 n.2 (5th Cir. 1978) ("Rule 41(a) speaks of dismissal of an action, and the plaintiff's elimination of a fragment of an action ... is more appropriately considered to be an amendment to the complaint under Rule 15."); *Transwitch Corp. v. Galazar Networks, Inc.*, 377 F. Supp. 2d 284, 288 (D. Mass. 2005) ("[t]he weight of authority is that Rule 15(a), as opposed to Rule 41(a)(2), applies to an amendment which drops some but not all of the claims in an action.") (citing cases).

- Properly construed, § 3730(b)(1) applies only during the government's 60-day investigatory period, and does not continue to apply after the Government has elected not to intervene. In *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715, 721-22 (9th Cir. 1994), the Ninth Circuit analyzed the legislative history and purpose behind § 3730(b) as a whole, and concluded that "Congress' intent to place full responsibility for False Claims Act litigation on private parties, absent early intervention by the government. . . is fundamentally inconsistent with the asserted 'absolute' right of the government to. . . force a private party to continue litigation." *Id.*; *see also United States ex rel. Hillinger v. Hercules, Inc.*, 80 F. Supp. 2d 1234, 1240-41 (D. Utah 1999) (agreeing with *Killingsworth*).

- Even if § 3730(b)(1) could apply here, both the Government and the Southern District of Florida consented to Ven-A-Care's decision to drop claims relating to Acyclovir. The Government raised no objection when Ven-A-Care sought leave to amend its own complaint to adopt the more limited ComplaintG1, and the Southern District of Florida granted Ven-A-Care's motion for leave so to amend its complaint. (Exs. K, L); *see Hercules*, 80 F. Supp. 2d at 1241-43 (noting the "outcome in this case would not change" even if § 3730(b)(1) applied, given the Government's extensive notice and analysis of relator's claims and decision not to intervene).

Thus, the Court should not allow the Government to use § 3730(b)(1) to revive claims that both it *and* the relator affirmatively decided not to pursue. The Acyclovir claims should be dismissed on this basis alone.

B. The Government Was Required To Seek Leave To File Its "First Amended Complaint," And Leave Should Be Denied Here.

Rule 15(a) provides that a "party may amend the party's pleading *once* as a matter of course at any time before a responsive pleading is served. . . [o]therwise a party may amend the party's pleading only by leave of court." (Emphasis added.) In this case, the Government filed its ComplaintG2 without seeking leave to amend, stating that it was entitled to amend under Rule 15(a). (*See* Dkt. 4280 at 1.) The Government is wrong and, consistent with the requirements of justice, the Government's attempt to amend its complaint should be rebuffed for this reason, too.

Qui tam suits under the FCA are by their nature brought "in the name of the Government." 31 U.S.C. § 3730(b)(1). Although filed by a private relator, the "United States is the real party in interest in a *qui tam* action under the FCA even if it is not controlling the litigation." *United States ex rel. Walker v. R&F Props. of Lake County, Inc.*, 433 F.3d 1349, 1359 (11th Cir. 2005) (citation and quotation marks omitted). When the United States elects to intervene in a *qui tam* action filed by a relator, it does not do so by filing a separate complaint or instituting a separate action; instead, it "proceeds with the action" and gains "primary responsibility for prosecuting the action." 31 U.S.C. § 3730(c)(1). Thus, where the

Government elects to intervene in a *qui tam* and files a complaint, "courts have consistently found that [the] intervening complaint filed by the Government must be viewed as an amendment of the relator's initial complaint rather than an independent complaint by a new party."[9]

Despite its caption, ComplaintG1 is, in fact, an amended complaint which superseded Ven-A-Care's ComplaintR5. Indeed, the Government itself recognizes this, as its ComplaintG1 expressly acknowledged that its filing was a continuation of a lawsuit brought by the relator. (*See* Ex. J at ¶¶ 7, 11.)[10] ComplaintG2, filed on June 4, 2007, is therefore not a "First Amended Complaint" (as it purports to be), but instead, an amendment of ComplaintG1 – itself an amended complaint. Because Rule 15(a) permits a party to amend only "*once* as a matter of course," the Government was required to seek leave of court before filing ComplaintG2; its failure to do so alone justifies dismissing ComplaintG2. *See* Fed. R. Civ. P. 15(a) (for second or successive amendments, "a party may amend the party's pleading only by leave of court or by written consent of the adverse party"); *Ritzer v. Gerovicap Pharm. Corp.*, 162 F.R.D. 642, 644 (D. Nev. 1995) (pleading filed without leave where it is required "has no legal effect").

Moreover, even had the Government properly sought leave to file ComplaintG2, the Court should have disallowed it as unjust. Amendments should be denied in the case of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Interpreting *Foman*, the First Circuit has held that leave to amend should be denied when the "facts upon which the proposed [amendment] rested

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[9] *United States ex rel. Wyke v. Am. Int'l, Inc.*, No. 01-60109, 2005 WL 1529669, at *2 (E.D. Mich. June 20, 2005) (citing cases); *see also Baylor*, 469 F.3d at 269 ("If the government decides to intervene, the intervention will almost always involve an amended complaint."); *United States ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 453 n.3 (E.D. Pa. 2004) ("The United States' complaint in intervention supersedes all allegations in the original complaint filed by the relator on behalf of the United States."); *United States ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d 69, 75 (D.D.C. 2003); 1 JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 4.05[B], at 4-173 (3d ed. 2006) (noting the "typical first step upon intervention is to file an amended complaint"); *cf. Rockwell*, 127 S. Ct. at 1409 (noting that, where the United States has intervened in a *qui tam*, "the Government's tactical decision to narrow the claims in a case" amends the relator's claims).

[10] And for good reason – the Government no doubt will contest this motion to dismiss, focused on the timeliness of complaints, by claiming that they "relate back" to one or more of the relator's *qui tam* complaints. *See generally* Fed. R. Civ. P. 15(c). The Government cannot have it both ways.

were known to [the amending party] all along" and where a "great deal of discovery had taken place without reference to the [new] theory." *Quaker State Oil Ref. Corp. v. Garrity Oil Co., Inc.*, 884 F.2d 1510, 1517-18 (1st Cir. 1989); *see also Palmer v. Champion Mortgage*, 465 F.3d 24, 31 (1st Cir. 2006) (affirming denial of leave to amend where "the plaintiff was aware of the factual predicate on which her new theory rested before she brought suit").

The prejudice to the non-amending party is particularly strong where leave to amend is sought "to restore allegations that the movant previously abandoned," because in such situations, "it is obvious that the movant did not suddenly discover a new cause of action." *Conroy Datsun Ltd. v. Nissan Motor Corp. (U.S.A.)*, 506 F. Supp. 1051, 1054 (N.D. Ill. 1980); *see also Waters v. Weyerhaeuser Mortgage Co.*, 582 F.2d 503, 507 (9th Cir. 1978) (denying leave to amend where "the amendment would allow the plaintiffs to litigate an issue they had earlier conceded, to the prejudice of the rights of the defendants"); *Ohio-Sealy Mattress Mfg. Co. v. Kaplan*, 90 F.R.D. 40, 42 (N.D. Ill. 1981) (denying attempt to revive dropped claims as unjust, where plaintiff did not make "an unwitting omission in the pleadings but a conscious decision which has shaped the conduct of this litigation for the past seventeen months"); *Friedman v. Transamerica Corp.*, 5 F.R.D. 115, 116 (D. Del. 1946) (denying amendment where "the 'new' matter sought to be incorporated into the complaint was once included in the original and first amended complaint and later was abandoned or deleted when plaintiffs filed their second amended complaint").

Under this clear law, the Government should not be granted leave to add claims relating to Acyclovir. The Government has been aware of these claims since ComplaintR3 was filed in August 1997. It already expressly declined to intervene in these claims when it filed ComplaintG1 and its notice of intervention in March 2006. (*See* Exs. I, J.) Only now, 15 months after taking over the case, does the Government seek this amendment, without any explanation as to why these claims must be pursued now.

Moreover, allowing the Government to revive the Acyclovir claims now would severely prejudice Abbott. The parties are already nearly two-thirds of the way through the fact discovery period. Abbott's discovery efforts—and the Government's delayed responses to those efforts—have focused on the NDCs and J-Codes named in the Government's ComplaintG1. Abbott would have to re-serve

discovery focused on Acyclovir—and wait months for the federal and state governments to respond to those requests. Abbott would also have to re-depose witnesses in order to ask them questions focused on Acyclovir and related issues. The prejudice that would result to Abbott, and to the discovery schedule in this case (where fact discovery is set to close on December 31 of this year), is manifest. For this reason, too, the Government should not be permitted to add these dropped Acyclovir claims now.

C. The Government Has Not Made, And Cannot Make, The Showing Of Good Cause Necessary For Its Attempted Late Intervention As To Acyclovir.

The new Acyclovir claims should be barred for yet a third reason: Even if Ven-A-Care had any such claims for the Government to intervene in (and it does not), and even if leave to amend had been sought (it was not) and could properly be granted (it cannot), the FCA itself prohibits the Government from adding these claims now.

When the Government elects not to intervene in a *qui tam* action, it may intervene later only by showing good cause. *See* 31 U.S.C. § 3730(c). The legislative history indicates that the rationale behind allowing late intervention is that "new evidence discovered after the [intervention decision] could escalate the magnitude or complexity of the fraud, causing the Government to reevaluate its initial assessment or making it difficult for the qui tam relator to litigate alone." S. Rep. 99-345 at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5291. Thus, "[i]n those situations where new and significant evidence is found and the Government can show 'good cause' for intervening . . . the court may allow the Government to take over the suit." *Id.* at 26-27, *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5291-92.

Here, claims regarding Acyclovir were among those made in relator's ComplaintR3 in 1997—in fact, Acyclovir was provided as a specific example of Abbott's alleged "marketing of the spread." (*See* Ex. F at 25-27.) The Acyclovir claims were still touted by Ven-A-Care in ComplaintR5 in 2002. (*See* Ex. H at Ex. 6, p. 5.) Nevertheless, when the Government filed ComplaintG1 in 2006, it expressly listed the specific drugs for which it sought to intervene, declining to intervene in the rest (including Acyclovir). Accordingly, any attempt to intervene as to Acyclovir claims now (assuming that Ven-A-Care had such claims pending, which it does not) requires a showing of "good cause." *See* 31 U.S.C. § 3730(c)(3).

The Government has not even tried to show good cause here, and this failure requires the dismissal of the Acyclovir claims. In any event, the Government could not possibly show good cause to intervene in the Acyclovir claims, given that none of the situations specified in the legislative history is present here. The Government cannot credibly allege that it obtained "new and significant" evidence in this case regarding Acyclovir. These claims were alleged by Ven-A-Care in ComplaintR3, ComplaintR4, and ComplaintR5, and thus the Government was fully aware as much as ten years ago of the alleged price spread between reported AWP and Abbott's discounted prices, and the alleged marketing of that spread, since at least 1997. For this reason, too, the Government cannot revive these claims now.

II. THE BULK OF THE GOVERNMENT'S CLAIMS ARE TIME-BARRED AND ARE NOT SAVED BY RELATION-BACK.

In addition to the new Acyclovir claims, the bulk of the Government's other claims based on the FCA are untimely, and should be dismissed. The FCA provides that no civil action may be brought "more than 6 years after the date on which the violation . . . is committed," or "3 years after the date when facts material to the right of action are known or reasonably should have been known by [the government]," "whichever occurs last." 31 U.S.C. § 3731(b)(1),(2). Under the latter provision, a claim may "in no event [be filed] more than 10 years after the date on which the violation is committed." *Id.* § 3731(b)(2). Time-barred claims must be dismissed. *See Jones v. Bock*, 127 S. Ct. 910, 920-21 (2007).

The Government filed its ComplaintG1 on March 17, 2006, intervening in Ven-A-Care's under seal *qui tam*, and alleging that Abbott filed or caused to be filed false claims relating to 44 specific NDCs and 11 J-Codes.[11] With the exception of the four J-Codes never alleged as to Abbott in any of Ven-A-Care's *qui tam* complaints, the Government was unquestionably aware of *all* the claims contained in its

[11] The Government's ComplaintG1 and ComplaintG2 are not terribly clear as to the dates on which the alleged transactions supporting its FCA counts occurred. ComplaintG1 states that Abbott "defrauded" the United States "[f]rom at least on or before January 1, 1991, and continuing through January 2001." (Ex. J at 16). But when discussing specific NDCs, ComplaintG1 states that the fraud with respect to Vancomycin occurred "from approximately 1989 through 2001," (*id.* at 19), and suggests a start date of 1993 and an end date of 2000 for false claims related to "Large Volume Parenterals" (LVPs). (*Id.* at 24-26.) ComplaintG2 sheds some light on the matter. Though it repeats that fraud occurred "[f]rom at least on or before January 1, 1991, and continuing through 2001," making the same allegations regarding Vancomycin and LVPs as the Complaint in Intervention, it does specifically note that the Acyclovir claims accrued starting April 22, 1997 and ending on April 30, 2001, the date that Abbott changed list prices for many of its drugs. (Dkt. 4281 at 16, 20, 25-29.) This date thus marks the end of the fraud as alleged by the United States.

initial Complaint since at least December 11, 2002, when the relator filed its ComplaintR5. Accordingly, the Government can receive no benefit from the three-year tolling provision of § 3731(b)(2)—as any tolling would have expired on December 11, 2005. The six-year FCA limitations period thus applies.

Unless the Government's claims are permitted to relate back to one or more of Ven-A-Care's *qui tam* complaints, recovery relating to allegedly false claims presented to the Government for payment prior to March 17, 2000—six years prior to the filing of ComplaintG1—is barred by the FCA's six-year statute of limitations. *United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995). And, even if the Court permitted the Government's claims to relate back to Ven-A-Care's *qui tam* complaints, a straightforward application of Rule 15(c) restricts the Government's recovery to a period of six years prior to the date that Ven-A-Care first included allegations relating to particular NDCs and J-Codes. These alternative arguments are set forth, in turn, below.

A. Relation-Back To Ven-A-Care's *Qui Tam* Complaints Is Not Permitted Because Those Complaints Were Sealed And Did Not Give Notice to Abbott.

Federal Rule 15(c)(2) provides that an "amendment of a pleading relates back to the date of the original pleading when . . . the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." The "linchpin to Rule 15(c) is notice before the limitations period expires." *Marsh v. Coleman Co.*, 774 F. Supp. 608, 612 (D. Kan. 1991) (citing *Schiavone v. Fortune*, 477 U.S. 21, 31 (1986)). But as the Second Circuit has held, because a relator's *qui tam* complaint "is distinctive for [its] secrecy," it cannot support relation back. *United States v. Baylor Univ. Med. Ctr.*, 469 F.3d 263, 269-70 (2d Cir. 2006).

In *Baylor*, the Government filed an untimely complaint in intervention in an FCA Medicare fraud case, and sought to relate it back to the relator's timely complaint. *See id.* at 268. The Court refused to allow relation back under Rule 15(c)(2).[12] It noted that, under 31 U.S.C. § 3730(b), a relator's "qui tam

[12] The *Baylor* court left undecided—because the parties did not raise it—the question of whether relation back of a Government's complaint under the FCA to a relator's complaint might be permitted under Rule 15(c)(1). *Id.* at 270. Rule 15(c)(1) provides that a later amended pleading may relate back to an original pleading when "relation back is permitted by the law that provides the statute of limitations applicable to the action." Rule 15(c)(1) was designed to help parties invoking the federal courts' *diversity* jurisdiction, who would be entitled to greater relation back under the state law involved in the case than they would under Rule 15(c)(2); that is not this case.

complaint must be filed in camera and must remain under seal" while the Government investigates the relator's claims in advance of deciding whether to intervene. *Id.* at 269. Thus, "[b]y design, the seal provision of § 3730(b) deprives the defendant in an FCA suit of the notice usually given by a complaint." *Id.* at 270. The Court held that "[b]ecause any relation back of subsequent filings to the original complaint is incompatible with the core requirement of notice under Rule 15(c)(2), continued running of the statute of limitations is warranted," at least until the Government files its complaint in intervention. *Id.* This was so even though Baylor had previously learned about the charges through informal channels. *See id.* at 270 n.8. Further, the court noted that the purposes of the FCA's statute of limitations could be undermined by excessive delay by the Government in unsealing a complaint. *See id.* at 270 n.10.

The circumstances that existed in *Baylor* are remarkably similar to the circumstances here. As in *Baylor*, although this case was filed by the relator in 1995, and although Abbott had been made informally aware of potential FCA charges for some time, Abbott did not receive formal notice of the particular claims against it until the case was unsealed and the Government filed ComplaintG1 on March 17, 2006—over a decade later. (Indeed, Abbott was not served with ComplaintG1 until May 26, 2006.) And the facts discovered to date in this case confirm the *Baylor* court's intuition, and this Court's expressed concern, that it is fundamentally unfair to allow relation-back to a complaint kept under seal for years by the Government. (Ex. M at 48 (Court notes the potential for "prejudice to the defendants": "I've actually had this debate with some members of my local U.S. Attorney's office: What about witness memories? People forget. Documents get lost, right? . . . [and defendants] bear the brunt of it[.]").)

(continued…)

Estate of Butler ex rel. Butler v. Maharishi Univ. of Mgmt., 460 F. Supp. 2d 1030, 1040 (S.D. Iowa 2006). Three district courts to have considered whether Rule 15(c)(1) permits the Government's FCA claims to relate back to relator complaints have therefore concluded that it does not. *See United States ex rel. Ortega v. Columbia Healthcare*, Inc., 240 F. Supp. 2d 8, 14 n.7 (D.D.C. 2003) (noting that Rule 15(c)(1) has "no application" to FCA claims; "Rule 15(c)(1) permits relation back when permitted by the applicable statute of limitations," and "[t]he FCA statute of limitations makes no mention of relation back."); *United States ex rel. Koch v. Koch Indus., Inc.*, 188 F.R.D. 617, 627 (N.D. Okla. 1999) ("The law that provides the statute of limitations applicable to this action is the FCA's statute of limitations at 31 U.S.C. § 3731(b). Section 3731(b) contains no provisions dealing with the relation back of amendments to complaints stating qui tam claims. Thus, Rule 15(c)(1) is not applicable to this case."); *United States ex rel. Colunga v. Hercules Inc.*, 1998 WL 310481, *2 (D. Utah 1998); *but cf. United States ex rel. Kaplan v. Metro. Ambulance & First Aid Corp.*, No. 00-Civ. 3010 (ERK) (JMA) (E.D.N.Y. July 5, 2007) (suggesting "inclin[ation]" to hold otherwise).

In this case, the Government kept Ven-A-Care's complaints under seal for 11 years. Throughout that time, the Government extended the seal period,[13] keeping the *qui tam* action hidden, and preventing Abbott from becoming active in discovery to preserve evidence needed to defend itself. Yet, during that decade-plus period, the Government was permitted to (and did) engage in extensive one-sided discovery against Abbott, as the pleadings recently released from seal confirm.[14]

While the Government was busy collecting evidence to support its case, however, it completely shirked its obligation to preserve evidence obviously relevant to this case, which Abbott would need to defend itself. Years' worth of relevant Government emails and correspondence were destroyed by the Government while this case was sealed. (*See* Ex. U at 90-93, 226-29, 240-41 (CMS has emails and electronic documents for only one of the 28 former CMS employees identified by the Government as having responsibility for the methodologies and procedures used in Medicare and Medicaid drug reimbursement)); Ex. V at 73, 77-78, 81-82, 84-85, 137-38 (CMS' 30(b)(6) designee on issues of document preservation testified that a litigation hold was not put in place for this case until January of 2007—months after Abbott noticed a deposition of an electronic records custodian—and that she was unaware of any steps taken to preserve or collect AWP-related documents at CMS until 2003, after defendants in the MDL served a subpoena on CMS).)

The Government continued to destroy evidence even *after* it was served in 2003 with third-party subpoenas in MDL 1456 and it was clear that documents relating to the Government's awareness and decision-making in the area of drug reimbursement were potentially relevant. For example, Thomas

[13] In support of such extensions, the Government repeatedly told the Court, *ex parte*, that "no defendant has expressed any reservations regarding the continuance of the seal." (*See* Ex. X at 10.) At least as to Abbott, those representations were misleading; Abbott was never asked whether it opposed the Government's *ex parte* requests for extensions, and certainly never agreed to the extraordinary length of the Government's delay in this case.

[14] (*See* Ex. W at 1-2 (Government's Aug. 20, 1997 Status Report: "[M]any meetings and conferences have been held with the representatives of the Medicaid programs of the states of Florida, Texas and New Jersey. . . . Preliminary discussions have been held with representatives of the Medicaid programs of other states as well. . . . [HHS-OIG] is in the process of preparing 'Inspector General' subpoenas for service upon each of the named defendants."); Ex. X at 3-4 (Government's Nov. 17, 1998 Status Report: "NAMFCU representatives have been gathering from all 50 states the specific pieces of information relating to the allegedly fraudulent reimbursement claims submitted by the providers who purchased defendants' drugs."); Ex. Y at 3-4 (Government's Feb. 21, 2002 Status Report: "Hundreds of boxes of documents with thousands of documents have now been received. Substantial effort has been devoted to reviewing these documents. At one point, a team of ten people were simultaneously reviewing the voluminous documents").)

Scully, a former CMS Administrator, testified that he used email extensively, including a daily email sent to all 4,000 CMS employees as to what he was doing on a given day. (*See* Ex. S at 79-80.) Mr. Scully testified that prescription drug reform and "fixing AWP" were his top priorities when he joined CMS. (*Id.* at 376-77, 381.) When Mr. Scully's personal counsel requested that CMS produce his emails in March or April of 2004, three to four months after he left CMS, he was told that they no longer existed. (*Id.* at 79-80.) Particularly noteworthy, Mr. Scully's emails appear to have been destroyed *at the same time as* CMS purportedly was gathering documents for the subpoena issued by MDL 1456 defendants.[15]

Time, too, has taken a toll. Repeatedly, Abbott has met with a lack of memory when it has asked state and federal Medicare and Medicaid officials what they knew about published drug prices, when they knew it, and why they continued to use those prices despite extensive contemporaneous evidence that the compendia-published AWP was substantially higher than real market prices. Witnesses have universally testified that they simply cannot recall much of anything given the passage of time. (*See, e.g.*, Ex. Q at 157 (former CMS employee Booth: "I'm 70 years old. I have not dealt with these issues for at least 13 years . . . ."); Ex. R at 46 (Former CMS Director DeParle: "Well, it's been about 15 years ago, so my memory of it is limited."); *id.* at 53 ("Q. Is it fair to say that if I had asked you in 1997 you would have a better memory of what occurred at the meeting? . . . A. I would hope so."); Ex. S at 147 (Former CMS Administrator Scully: ("Q. I think you mentioned earlier that this attempt to reduce reimbursement levels like many of the others ran into political difficulties during this time period, right? . . . THE WITNESS: I can't remember exactly that far back what the issues were, but yes, there was significant concern about the rule at the time, I believe."); Ex. P at 310-11 (former CMS Administrator Vladeck admitted the ability to review past emails would be a "very useful spur to the memory" of "things [he] had totally forgotten"); Ex. T at 496, 515-21, 546-60 (given passage of time, Mr. Vito unable to recall if he discussed the Barron's 1996 "Hooked on Drugs" article, or the details of OIG's work relating to drug pricing, at numerous meetings with state pharmacy representatives), 509-11 (unable to recall if he discussed large

[15] Indeed, with the exception of one CMS official who recently left the agency, it appears that CMS made no systematic effort to retain emails or electronic files of key employees. (See Ex. U at 108-09, 226-29, 240-41.)

spreads on home IV solutions with CMS), 346-47 (unable to recall the details of conversations with HCFA regarding an appropriate profit margin on drugs).)

In short, the concern of the *Baylor* court is manifest in this case: Abbott's ability to defend itself against the Government's serious accusations has been compromised by the Government's extraordinary delay and its destruction of evidence. Ven-A-Care's *qui tam* complaints should not, and as a matter of law cannot, support relation back. Accordingly, the proper result is to dismiss as untimely all FCA claims relating to transactions occurring before March 17, 2000. (*See* Ex. A, Column 1.)

B. In Any Event, Claims Regarding Any Particular NDC Or J-Code May Relate Back Only To The Complaint In Which It Was First Named.

Rule 15(c) governs the relation-back of amended complaints. It provides, in relevant part, that "[a]n amendment of a pleading relates back to the date of the original pleading when (1) relation back is permitted by the law that provides the statute of limitations applicable to the action, or (2) the claim or defense asserted in the amended pleading arose out of the same conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." As this Court suggested at argument on Dey's motion to dismiss, relation-back will not be allowed under Rule 15(c) just because the same general cause of action or theory of liability is pled. Rather, the original complaint must reference *the particular claim* to be asserted – in this case, a particular NDC or HCPCS J-Code.[16]

For instance, in *O'Loughlin v. National Railroad Passenger Corp.*, 928 F.2d 24, 25-26 (1st Cir. 1991), the plaintiff received on-the-job injuries twice within a few months, one on June 8 and the other on August 6. His original complaint alleged that on August 6, he "was injured due to unsafe and inadequate working conditions." *Id.* at 27. He amended his complaint to allege injury on June 8, but the Court found that, even though both situations involved injuries due to unsafe working conditions, the original complaint gave no indication that the specific claim being asserted was the June 8 injury. *See id.* Relation back was therefore disallowed. *See id.* Likewise, in *United States ex rel. Health Outcomes*

[16] (*See* Ex. M at 22 (Court suggests that, assuming the Court does not follow *Baylor*, "the second fall-back would be, at the very least, the[] [Government] can't be adding any new drugs" and getting relation back); *id.* at 41 (Court: "When there's a new . . . drug, . . . it's got to start from when that was first in the complaint."); *id.* (Court suggests "figur[ing] it out drug by drug as to whether it was the same transaction, scheme, occurrence, et cetera").)

Technologies v. Hallmark Health System, Inc., 409 F. Supp. 2d 43, 45 (D. Mass. 2006), the relators filed a complaint in early 1996, alleging that hospitals miscoded a specific medical procedure to receive a higher rate of reimbursement from the government. An amended complaint was later filed, alleging claims for that fraud for the years 1996 and 1997. *See id.* at 53. The court held that these claims could not relate back to the 1996 original complaint, as the new claims could not "expand or modify facts alleged in the earlier pleading because they were not asserted in the original complaint." *Id.*[17]

These authorities compel the conclusion that alleged false claims related to a discrete NDC or J-Code are different "conduct, transactions, or occurrences." A complaint alleging that a party made false claims regarding Code A simply does not contain facts sufficient to provide a party notice that it will also be held accountable for false claims for Code B. *See, e.g., Oja*, 440 F.3d at 1133; *Ill. Tool Works, Inc. v. Foster Grant Co., Inc.*, 395 F. Supp. 234, 250-51 (N.D. Ill. 1974) ("An alleged infringement of one patent is not the 'same conduct, transaction or occurrence' as the alleged infringement of another patent."). As such, for the purposes of this case, any alleged false claims regarding a particular drug code should be permitted relation-back only to the date the drug code was first alleged.

Because Ven-A-Care voluntarily dismissed ComplaintR1 as to Abbott Laboratories, no claims may relate back to that defunct complaint. *See, e.g., Jorge v. Rumsfeld*, 404 F.3d 556, 563 (1st Cir. 2005); *Harbor Ins. Co. v. Essman*, 918 F.2d 734, 737 n.3 (8th Cir. 1990) ("The relation-back doctrine of Rule 15(c) is inapplicable to the filing of a new complaint after an earlier action has been voluntarily dismissed. The voluntary dismissal of an action places the parties in a position as if the suit had never been filed."); *Dade County v. Rohr Indus., Inc.*, 826 F.2d 983, 989 (11th Cir. 1987) ("The district court

[17] Several other courts likewise have not permitted relation back of factually distinct claims merely because they allege violation of the same statute or are based on similar torts. *See, e.g., Oja v. U.S. Army Corps of Eng'rs*, 440 F.3d 1122, 1133-34 (9th Cir. 2006) (amendment adding a claim arising from unauthorized disclosure of personal information on a website in December 2000 did not relate back to complaint based on a disclosure in November 2000 at a different internet address); *In re Bausch & Lomb, Inc. Sec. Litig.*, 941 F. Supp. 1352, 1366 (W.D.N.Y. 1996) (no relation back where amended complaint included allegations based on an earlier press release that was not mentioned in the previous complaint and "constitute[d] a separate alleged act of fraud"); *see generally* 6A CHARLES A. WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 1497 (2d ed. 1990) ("When plaintiff attempts to allege an entirely different transaction by amendment, Rule 15(c) will not authorize relation back. For example, amendments alleging . . . a separate violation of the same statute may be subject to the defense of statute of limitations because of a failure to meet the transaction standard.").

erred in applying the relation back doctrine to the filing of a new second complaint" as "the subsequent voluntary dismissal of the federal action has the effect of placing the parties in a position as if the suit had never been filed."). Rather, because Abbott was re-added in the August 12, 1997 ComplaintR3, that is the earliest possible complaint for relation back purposes, as this Court has already recognized. (Ex. M at 41 ("When there's a new defendant . . . it's got to start from when that was first in the complaint.").)

As to possible relation back dates (*see* Ex. A, Column 2), assuming it is permitted at all:

- The 28 claims raised for the first time in ComplaintR3 (five of which were raised in ComplaintR1, but as set out above, that does not matter) were not alleged until August 12, 1997; because they may relate back only to that complaint, all claims accruing prior to August 12, 1991 are time barred.[18]

- The 25 claims first raised in ComplaintR5 were not alleged until December 11, 2002; because they may relate back only to that complaint, and thus all claims prior to December 11, 1996 are time barred.

- Finally, assuming that the four HCPCS codes not contained in any *qui tam* complaint are properly in this case (and they are not), they were first alleged in ComplaintG1, filed March 17, 2006; because they may relate back only to that complaint, all claims prior to March 17, 2000 are time-barred.

CONCLUSION

For the foregoing reasons, Abbott's Motion to Dismiss or Partially Dismiss the First Amended Complaint should be granted. The Court should:

- Dismiss ComplaintG2, with its new Acyclovir allegations, in its entirety because the United States did not seek leave to amend; deny leave to amend to the extent that ComplaintG1 seeks to add Acyclovir claims; dismiss the Acyclovir claims because there were no Acyclovir claims in ComplaintR6 to intervene in; or dismiss the Acyclovir claims because the United States cannot show good cause to intervene in them now, having declined to do so earlier.

- Dismiss the 4 new HCPCS J-Code claims, because the relator never made such allegations and thus there were no such claims in which the United States could intervene.

- Hold that the statute of limitations bars all claims which accrued 6 years prior to the unsealing of ComplaintG1 on March 17, 2006 (as set out in Column 1 of Exhibit A), or alternatively, dismiss claims related to particular NDC and HCPCS J-Codes that accrued more than 6 years before the date such claims were first mentioned in any complaint (as set out in Column 2 of Exhibit A). Otherwise, at the very least, hold that ComplaintR1, from which Abbott was dismissed, cannot be used for relation back (as set out in Column 3 of Exhibit A); ComplaintR3 is the first possible complaint for relation back.

[18] The United States has alleged that the Acyclovir claims did not accrue until April 22, 1997; thus, even if not otherwise dismissed, there are no Acyclovir claims before that date. (Dkt. 4281 at 27-29.)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS OR PARTIALLY DISMISS THE FIRST AMENDED COMPLAINT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 17th day of July, 2007.

/s/ David S. Torborg
David S. Torborg